SEVEN publicações acadêmicas

CHAPTER 33

ENSURING ETHICS IN THE USE OF SENSITIVE DATABASES: A SCOPING REVIEW

https://doi.org/10.56238/sevened2024.029-033

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ABSTRACT

Introduction: Despite the legal guidelines, it is necessary to detail the strategies used by controllers and operators of health databases, with a view to directing future studies and to inform institutions involved in the protection of research participants. Objective: To identify the main problems for the protection of patient data and strategies to mitigate the problems pointed out, through a scoping review. Methods: In this study, the Joanna Briggs Institute (JBI) methodology for scoping reviews was followed. The PCC (Population, Concept and Context) strategy was used to formulate our research question: "How to conduct research in health databases, ensuring anonymity and attention to patients?" To identify relevant articles, the following search algorithm was applied: (research or "Research Ethics Committee") and (Ethics) and (technology or responsibility or security for "protecting information" or "Big Data" or "Patient Safety" or "Electronic patient record"). Original articles available in English, Portuguese and Spanish were selected from the Scielo, Pubmed and Scopus databases. The inclusion criteria were: articles that addressed problems and alternatives related to data security, in addition to explaining the origin of the research group. Individual searches were conducted, articles were selected, and agreement between reviewers was verified. The complete reading of the selected articles and the extraction of the data were done with the help of the Mendeley software and the Rayyan website. Results: A total of 947 articles were found. Of these, 88 were duplicates; The reviewers showed 86% (n=815) agreement between the articles that met the inclusion criteria, resulting in a total of 43 articles included. The 43 articles were read in full, in order to apply the exclusion criteria, resulting in the selection of 17 works. The prevalence of the problems identified was focused on the lack of a standardized system that can guarantee the confidentiality and reliability of the data collected. The alternatives to mitigate the problems identified showed prevalence in the implementation of specific legislation, for research involving the use of sensitive databases. Conclusion: The lack of standardized systems to ensure the reliability and confidentiality of the collected data was the main problem identified. As a mitigation strategy, the implementation of specific laws for research that uses sensitive databases was suggested.

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Keywords: Research Ethics. Database. Digital Security.

INTRODUCTION

Sensitive data can be defined as sensitive information that requires protection due to its private nature and potential for misuse. This concept encompasses data related to an individual's medical history, treatments, and conditions that, if disclosed without consent, could lead to discrimination or stigmatization. Protecting this data is crucial for maintaining patient confidentiality and trust in healthcare systems (Prasser *et al.*, 2018). Sensitive data on racial or ethnic origin, religious belief, political opinion, membership of unions or organizations, data about sex life, and genetic or biometric data may also be considered (Brazil. Presidency of the Republic., 2018).

International regulations for the protection of sensitive patient data in databases are shaped by a complex interplay of privacy laws, public health needs, and technological advancements. These regulations aim to balance the protection of individual privacy with the need for data sharing for research purposes and public policy decision-making.

A relevant aspect in this discussion is the ownership of data, that is, who has the right to access and use such information, as well as the ethical implications of this ownership. Rodwin and Rodwin (2010) (Rodwin, 2010) advocated for public ownership of patient data to avoid monopolies and ensure that data is used for advancements in health and safety. The authors suggested that federal laws require the anonymous communication of data to public authorities, which can then oversee its use by private entities. For the authors, public ownership allows for greater oversight and protection of patient confidentiality compared to private ownership, which could restrict public and private use of data. This approach would not only promote transparency but also encourage collaborative research efforts that could lead to significant advancements in medical science.

However, the implementation of such policies raises questions about the balance between patient privacy and the potential benefits of data sharing for research and public health initiatives. In this context, regulatory restrictions on access and manipulation of data are important. In several countries, the use of clinical data is strongly regulated to protect patient privacy. These regulations are crucial to prevent misuse, but they also pose challenges for translational research (Ahalt *et al.*, 2019). Thus, innovative approaches should be developed for scientific knowledge of clinical data and, at the same time, for adherence to these regulatory constraints, such as an integrated clinical and environmental exposure service, which would allow open access to observational patient data integrated with environmental exposure data.

In the United States of America (USA), the protection of patients in databases is mainly governed by the Health Insurance Portability and Accountability Act (HIPAA),

published in 1996, which established national standards for the privacy and security of health information, including the need for data use consent and de-identification processes. Despite the initial framework, the U.S. also regulates privacy by industry and by state, which means that different laws apply to different domains. This fragmented approach can lead to inconsistencies and gaps in protection, prompting calls for a more unified framework that addresses the complexities of digital data sharing and privacy in the modern era (Kaplan, 2016).

Despite the criticisms and limitations, HIPAA is considered a regulatory milestone in the area. An example is the age limit of subjects to allow access to their data. Age is information that can help identify subjects, since the population tends to decrease in higher age strata and the identification of older older people becomes feasible, especially in smaller communities. According to HIPAA, the age limit for accessing and handling data is 90 years old. To Moffatt and Leshin (Moffatt; Leshin, 2024), this determination must undergo constant revision, as population longevity increases and the implications for data privacy must accompany such changes. The authors suggest increasing the upper age limit for access to and manipulation of health data for at least two more years, with regular updates of these limits in line with new demographic data and ethical standards considerations.

In the European Union (EU), the main regulatory framework is the General Data Protection Regulation (GDPR) - approved in 2016 and in force since 2018 - which defined a standard for data protection and privacy, influencing how researchers can access and use clinical data in member states. The GDPR represented a significant reform of data protection laws, emphasizing strict privacy standards and influenced global data privacy laws (Behrendt *et al.*, 2018).

As for recommended strategies, both the U.S. and the EU focus on de-identification as a method for privacy protection. This aspect involves removing or changing information that can identify individuals. However, the effectiveness and sufficiency of de-identification is debated, as it assumes that no harm to privacy occurs if individuals are not identified (Kaplan, 2016).

Thus, there is a global trend to harmonize data privacy standards, with increased adherence of countries to the elements of the GDPR. This convergence is driven by both legal obligations and voluntary business practices (Greenleaf, 2018). However, challenges remain, such as regional agreements with lower standards and free trade agreements that may run afoul of strict data protection laws. A strategy that tries to promote the ethical exchange of sensitive data between countries was the so-called "*Safe Harbor*". This program was created by the U.S. Department of Commerce and the European Commission

to overcome differences in approach to data privacy between the two continents by facilitating the secure sharing of information.

In Brazil, the General Data Protection Law (LGPD) emphasized the need for free and informed consent for the acquisition and handling of personal and/or sensitive information, as well as the formulation of security measures aimed at protecting databases. These guidelines included restrictions on access and unauthorized exploitation, audits to maintain the integrity and confidentiality of data, and anonymization or pseudonymization protocols, in accordance with good data governance (Brazil. Presidency of the Republic., 2018).

While national and international regulations strive to protect patient data, they must also adapt to the evolving landscape of digital health and so-called "big data." The balance between privacy and data utility remains a critical challenge, requiring ongoing dialogue and innovation in regulatory frameworks and local database management strategies. Despite the legal guidelines, it is necessary to detail the strategies used by controllers and operators of health databases, with a view to directing future studies and to inform institutions involved in the protection of research participants, such as Research Ethics Committees. Thus, the objective of the present study was to identify the main problems for the protection of patient data and strategies to mitigate the problems pointed out, through a scoping review. This review will cover methodologies and frameworks currently in use, highlighting best practices and potential areas for improvement in data governance.

METHODS

The conduct of this study followed the Joanna Briggs Institute (JBI) Evidence Synthesis methodology for Scoping Reviews of the (Peters et al., 2020). For the preparation of the present study, the Preferred Reporting Items for Systematic Review and Meta-Analysis for Scoping Review (PRISMA-ScR) protocol was adopted (Tricco et al., 2018; Page et al., 2021).

Likewise, the Population, Concept and Context (PCC) strategy was also used to formulate the research question, which was defined as follows: a) Population: research; b) Concept: ethics; c) Context: data security. The guiding question of the research was: How to conduct investigations in health databases ensuring anonymity and protection of patients?

Such a question reflects a crucial challenge at the intersection of ethics, technology, and public health. As the volume of data collected and stored increases, the need to ensure the privacy of individuals becomes even more urgent. Effective investigations must balance the pursuit of scientific knowledge with the responsibility to protect sensitive information, avoiding unwanted exposures that could compromise patient safety. In addition, this

problem requires the analysis of ethical practices and the development of guidelines that guide researchers in the manipulation of data, ensuring that the solutions adopted respect the autonomy and dignity of the individuals involved. Therefore, the investigation not only seeks answers, but also proposes an ongoing dialogue on best practices in a rapidly evolving landscape.

For this purpose, a search was carried out in the National Library of Medicine - PubMed databases and in the Virtual Health Library (VHL) website to identify relevant keywords, resulting in the following search algorithm: (research or "Research Ethics Committee") and (Ethics) and (technology or responsibility or security for "protecting information" or "Big Data" or "Patient Safety" or "Electronic patient record").

SAMPLE SELECTION

The inclusion criteria established were: original articles, available in full, in English, Portuguese and Spanish, located in the SciELO, PubMed and Scopus databases, which dealt with the management of patient data. On the other hand, the exclusion criteria were defined as articles that did not effectively address the topic, that did not simultaneously discuss the problems and alternatives for data security, or that did not specify the origin of their research group.

This exclusion aimed to maintain a standard of quality in the sources used, ensuring that only rigorous and well-founded studies were considered. In this way, we sought to eliminate potential biases and ensure that the evidence presented was robust and contributed significantly to the discussion on ethics in the management of patient data.

PROCEDURES

The study adopted the peer review strategy to ensure rigorous verification and proper application of the inclusion and exclusion criteria. Each reviewer performed some steps individually: Stage a) Searches in the selected databases, using the algorithm for identifying relevant words in the titles, abstracts and keywords, applying the filters for the Portuguese, English and Spanish languages; for experimental designs of observational articles and clinical trials; for the articles available in full. Stage b) Selection of articles according to the inclusion criteria. Stage c) Verification of the agreement between the reviewers in relation to the inclusion criteria. Step d) Application of the exclusion criteria by each reviewer. Stage e) Verification of the agreement between the reviewers on the exclusion criteria. Stage f) Completion of the full reading of the selected articles. Stage g) Discussion and extraction of data from the chosen articles. Stage h) Data extraction and analysis using the Mendeley

reference management software and the specialized revision management platform Rayyan.

This strategy sought to ensure that each stage of the article selection and analysis process was carried out with greater precision and impartiality. The combination of thoughtful search strategies and cross-reviewer validation not only aimed to strengthen the quality of the evidence collected, but also to ensure the relevance and integrity of the extracted data.

OUTCOMES

For each selected article, several aspects were recorded, such as the origin of the publication group, the impact factor of the published journal, the number of citations until August 2024, the year of publication, the identification of problems related to data security, the proposed solutions, and the relevant legislation in force.

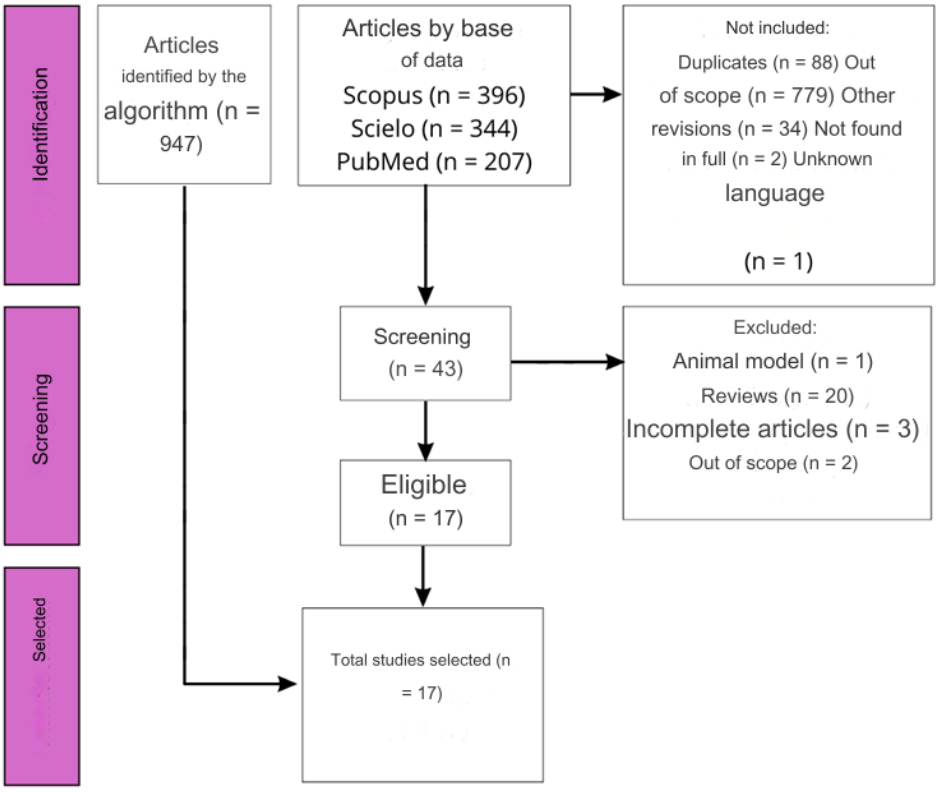
Problems and mitigation strategies were recategorized to facilitate identification by frequency and analyzed with the help of the "https://wordart.com/create" platform. To assess the repercussion of each article, the number of citations up to September 2024, obtained from the "https://scholar.google.com/" website, was considered. The "https://researchrabbitapp.com/home" site was used to verify the impact of the works, where the relationship between them of the selected studies was necessarily observed, as well as their potential to influence studies with similar themes.

This approach allowed for a comprehensive and systematic analysis of the data, contributing to a deeper understanding of the research questions.

RESULTS

In Pubmed, 207 articles were identified, in Scopus 396 and in Scielo 344, with a total of 947 articles. 88 duplicates were identified, the 3 reviewers who participated in the selection phase regarding the readings of titles, abstracts and keywords showed 86% (n=815) agreement between the articles that met the inclusion criteria, the 14% (n=128) of the articles that presented divergence in at least one of the decisions were reread, and the conflicts were resolved, resulting in a total of 43 items included. The 43 articles were presented to the rest of the authors and read in full, in order to apply the exclusion criteria, resulting in the exclusion of 26 works and the selection of 17 works, as shown in figure 1.

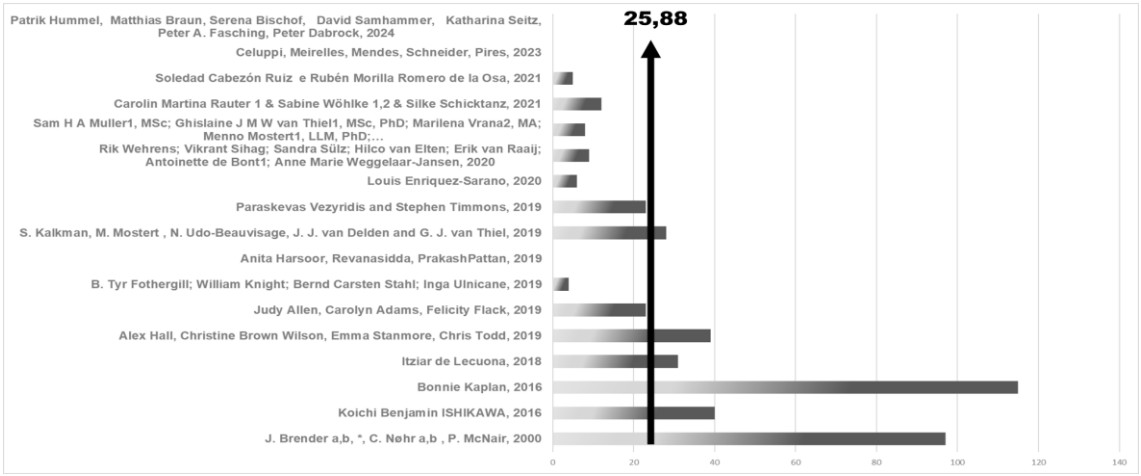
Figure 1. Flowchart for the selection of the works identified in the different databases.



The 17 selected articles were published between the years 2000 and 2024, where 82.4% are available in English, 11.8% in Spanish and 5.9% in Portuguese. As for the origin of the study groups, only one multicenter study was identified, 11 studies were developed in Europe, 2 studies from Asia, 1 from South America and 2 from North America. Its experimental designs showed a predominance of qualitative studies (n=13), followed by 2 qualitative/quantitative studies, 1 cross-sectional study and one case study.

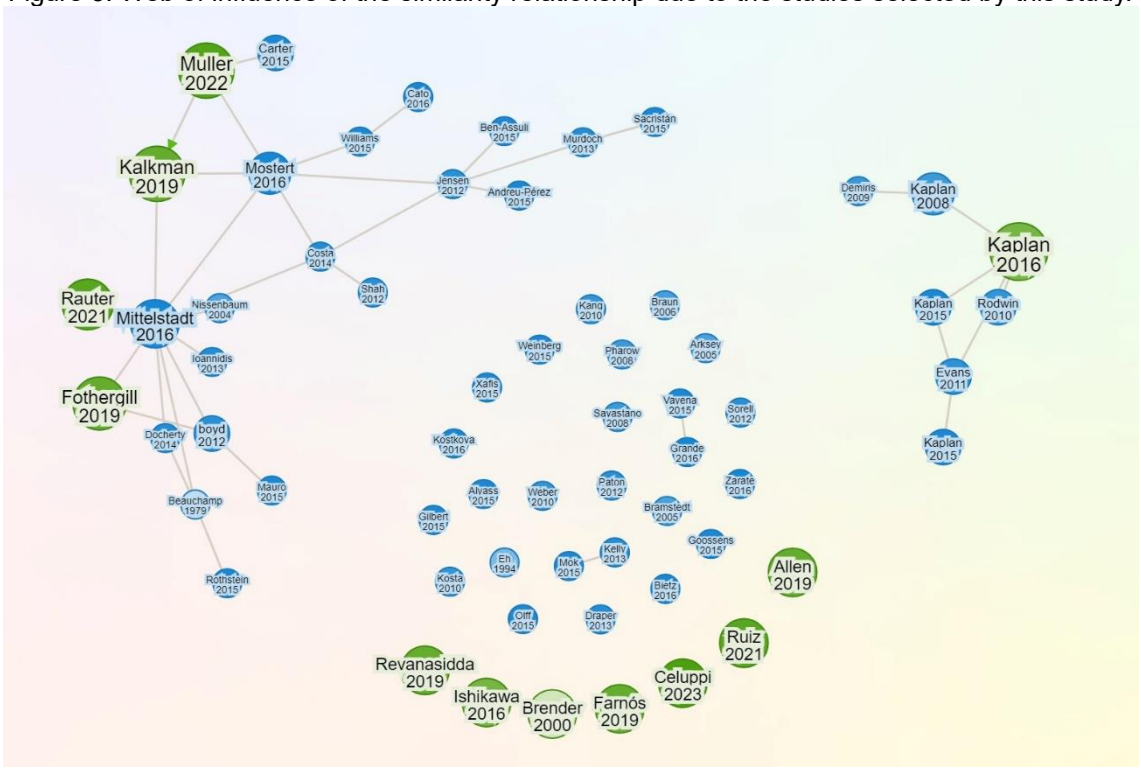
The number of citations of each selected article was evaluated, thus there was a variation where 2 articles did not present any citations so far, and one article presented 115 citations, and with an average of 25.88 citations, as shown in figure 2.

Figure 2. Absolute frequency of citations (up to September, 2024), showing the degree of repercussion of each study.



The works selected by this article generate a worldwide impact, deliberating on the similarity between other works that address the same theme, as presented in figure 3.

Figure 3. Web of influence of the similarity relationship due to the studies selected by this study.



All articles presented different concerns related to the use of sensitive databases, however the prevalence of the problems identified was focused on the lack of a standardized system that guarantees the confidentiality and reliability of the data collected. The alternatives to mitigate the problems identified were also diverse, but with prevalence in the implementation of specific legislation, for research involving the use of sensitive databases, as identified in figure 4.

Figure 4. Word clouds, referring to the incidence of problems and strategies to mitigate the problems (n=17).

DISCUSSION

A database with information about people's health, as well as all research, must lend itself to contributing to the good of humanity (Mann; Savuscu; Sahakian, 2016), must be able to *feedback* concise and accurate about the patient's health status, regardless of the time when the collection was carried out (Fothergill, B. Tyr *et al.*, 2019; O'Brien *et al.*, 2019), ensuring that diagnosis, treatment and prognosis are offered efficiently.

Some studies point to difficulties in ensuring that these data are not used with the objective of manipulating unwanted outcomes in relation to their confidentiality (de Lecuona, 2019; Ishikawa, 2016; Kalkman *et al.*, 2019; Rauter, Carolin Martina; Wöhlke; Schicktanz, 2021). In a review conducted by Fernández-Alemán (Fernández-Alemán *et al.*, 2013), the group points out the need to use protocols in the ISO 27799 standard, where they present international guidelines for data security regarding personal health information.

Data management still goes through a structure where data are collected by technicians who will not necessarily be responsible for patient care, therefore, they must be redirected to the competent health team, capable of interpreting, treating and deliberating on the therapeutic alternatives arising from the data (Lisbon *et al.*, 2023; Wen, 2008). This data transfer process was pointed out as a recurrent problem in the studies selected by this review (Celuppi *et al.*, 2023; Harsur; Revanasiddha, 2019; Hummel, Patrick *et al.*, 2024; Kalkman *et al.*, 2019; Soledad Cabezón Ruiz; Rubén Morilla Romero de la Osa, 2021).

Following the line of the need to develop a data management system, pointing out both the need for anonymization and de-identification, the encryption of data transfer and data curation by a legal guardian, point out the need for an integrated system with standardized language (Allen, Judy; Adams; Flack, 2019; Brender, J.; Nøhr; McNair, 2000; Harsoor; Revanasidda, 2019; Hummel, Patrik *et al.*, 2024; Ishikawa, 2016). An integrated management system for the data collected would facilitate access for both patients and

other professionals who can assist in the treatments, in addition to generating autonomy and allowing the management of their own data by the patient, as pointed out by the work of Cerami and collaborators (Cerami *et al.*, 2012), where the implementation of a database of cancer patients is investigated.

The present review sought not only to glimpse the scenario of ethical aspects of the use of sensitive data in a single country, but also observed different regulations responsible for regulating the legal guidelines of different parts of the world. In Brazil, the implementation of Law 14,874/2024 emerges with the need to register, inspect, and submit health databases to the system of Human Research Ethics Committees, in order to resolve the unwanted and/or inappropriate use of the data collected.

In this review, 5 studies point to the need to review local legislation, in order to generate objective, concise and cohesive regulation on the subject pointed out (Celuppi *et al.*, 2023; Hummel, P. *et al.*, 2024; Kalkman *et al.*, 2019; Ruiz; de la Osa, 2021; Wehrens *et al.*, 2020). The process of implementing a law is not only up to the regulatory entities, but also to all the active agents involved in the process of using health databases, in addition to taking advantage of the different systems, reflecting on the practices of data use (Favaretto; De Clercq; Elger, 2019).

The review presents interesting issues regarding the training for the use of the database, from the population, considered as the end user, to the professionals who manage them (Allen, J.; Adams; Flack, 2019; Brender, J; Nøhr; McNair, 2000; Celuppi *et al.*, 2023; Fothergill, B.T. *et al.*, 2019; Muller *et al.*, 2022; Rauter, C.M.; Wöhlke; Schicktanz, 2021), must participate in continuing education, for the conscious and ethical use of the information inserted in this system. The study by Schillinger et al. (Schillinger *et al.*, 2002), presents data on health literacy on aspects related to people with diabetes, and states that people with skills to understand the instructions given by health professionals are more likely to benefit from an uncomplicated prognosis, and that professionals who have the necessary resources to manipulate data management systems have a better chance of successful treatment (Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, 1999; Koh *et al.*, 2008; Veras *et al.*, 2024).

One future outlook observed and alerted by 3 studies was the monetization risk of healthcare databases (Louis Enriquez-Sarano, 2020; Ruiz; de la Osa, 2021; Vezyridis; Timmons, 2019). Having seen the context presented by the studies, it is worth emphasizing the need for regulation, protecting not only the use of data, but also the guarantee of access by patients to their own data and their protection against misuse and unauthorized use (Surroca; Tribó; Waddock, 2010).

CONCLUSION

Throughout this analysis, a variety of articles on issues related to the handling of sensitive data in research with human subjects were examined. The main problem identified was the lack of standardized systems to ensure the reliability and confidentiality of the data collected. However, options to mitigate these difficulties were also identified. The implementation of specific laws for research using sensitive databases proved to have been one of the solutions with the highest suggested incidence. This regulation not only protects participants, but also gives researchers clear guidelines to ensure that data is treated with respect and care. Finally, to preserve public trust and promote scientific advancements, it is essential to follow ethical research practices.

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